

May 24, 2021

Via Electronic Submission

Office of Environmental Health Hazard Assessment
Proposition 65 Implementation
P.O. Box 4010, MS-12B
Sacramento, California 95812-4010
<https://oehha.ca.gov/comments>

RE: Comments on OEHHA’s Proposed Amendments to Article 6 ‘Clear and Reasonable Warnings’ for Cannabis (Marijuana) Smoke and Delta-9-Tetrahydrocannabinol (Delta-9-THC) Exposures; New Sections 25607.38 – 25607.47

To Whom It May Concern:

The Personal Care Products Council (PCPC)¹ would like to thank the Office of Environmental Health Hazard Assessment’s (OEHHA) for the opportunity to provide feedback on its proposed amendments to Article 6, Clear and Reasonable Warnings under Proposition 65. OEHHA has proposed adopting tailored safe harbor warnings for, *inter alia*, delta-9-THC (THC) exposures, and our comments are limited to the proposed warnings for THC in dermally applied products.²

Dermally Applied Products

PCPC fully supports and agrees with OEHHA’s conclusion that no warning is required for dermally applied products³ containing “trace but unquantifiable” levels of THC:

*[W]here products such as topical lotions made with CBD or other cannabinoids may have trace but unquantifiable levels of delta-9-THC, no warning is required.*⁴

¹ Based in Washington, D.C., the Personal Care Products Council (PCPC) is the leading national trade association representing global cosmetics and personal care products companies. Founded in 1894, PCPC’s approximately 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S.

² Proposed “Sections 25607.44 and 25607.45 – Delta-9-THC from Dermally Applied Products Exposure Warnings – Methods of Transmission and Content.”

³ Please note we also urge OEHHA to change any references from “topical lotions” to “topical cosmetics” in order to avoid any implication that dermally applied products are limited to just “lotion” forms. There are several topically applied cosmetics, beyond lotions, that should be included (e.g., lip balms).

⁴ Initial Statement of Reasons, Feb 2021, Pg. 6.

Indeed, OEHHA correctly notes that CBD is not a Prop 65 listed chemical, and its presence in dermally applied products does not require a warning where vanishingly low levels of THC do not result in an exposure under the regulations:

*CBD is not on the Proposition 65 list and lotions made with CBD, other cannabinoids, or other purified extracts of the cannabis plants - that do not cause exposures to delta-9-THC or other Proposition 65 listed chemicals within the meaning of Section 25249.10(c) of the Health and Safety Code - do not require a warning. Added CBD may have trace but unquantifiable levels of delta-9-THC, and its presence in products should not trigger a warning.*⁵

PCPC agrees with OEHHA's rationale and position; nevertheless, there remains ambiguity around the terms "trace but unquantifiable", which could be interpreted differently by different companies. Indeed, the term "unquantifiable" itself is extremely problematic and makes no sense when joined with the term "trace".

Consequently, PCPC respectfully requests that OEHHA (1) remove the word "unquantifiable" and only use the term "trace" in reference to the presence of THC; and (2) define what it means by "trace" in order to provide regulatory certainty for those companies that sell topical cosmetic products containing CBD in the state of California. Absent a definition of "trace", companies are at risk of having to defend enforcement actions in which trace levels of THC are detected and no warning provided, with enforcers insisting that industry bears the burden to prove that the trace amount detected poses no significant or observable risk.

In making this request, PCPC strongly encourages OEHHA to consider and align with federal policy. The 2018 Farm Bill essentially legalized hemp – removing it from the Controlled Substance Act – and making it legal to grow, harvest, transport and market under certain conditions. Importantly, the bill defined 'hemp' as:

"[T]he plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, **cannabinoids**, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of **not more than 0.3 percent** on a dry weight basis."⁶ (Emphasis added.)

Congress recognized that the *Cannabis Sativa* L plant has different strains – THC-rich marijuana and THC-deficient, fiber-rich hemp – and therefore purposely regulated them differently. This difference resulted in the removal of hemp from the Controlled Substances Act and increased public awareness and acceptance of the many potential benefits of industrial hemp and its derivatives, such as hempseed oil, extracts, and other hemp-derived ingredients.

⁵ Id., pg. 17.

⁶ Agriculture Improvement Act of 2018, Public Law 115–334 (Dec. 20, 2018), Sec. 10113, Definitions.

As a result, companies growing and selling hemp and hemp-derived CBD products now take steps to ensure that there is 0.3% or less THC present in ingredients, a level that federal law arguably views as “trace”.

We, therefore, respectfully request that OEHHA remove the word “unquantifiable” and define “trace” as 0.3% or less THC, thereby aligning with federal law, avoiding potential market disruption, obviating the need for unnecessary exposure warnings where there is no risk, and providing much needed certainty to the regulated community.

Thank you for the opportunity to provide comment.

A handwritten signature in black ink, appearing to read "Thomas Myers", with a long horizontal flourish extending to the right.

Thomas Myers
EVP-Legal and General Counsel